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Transmittal (2 pages); and

Supplemental Reply Brief (14 pages).

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Atty. Dkt. No. 030427-0108

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Børge KRINGELUM, *et al.*
Title:	METHOD FOR SUPPLY OF STARTER CULTURES HAVING A CONSISTENT QUALITY
Appl. No.:	09/813,292
Filing Date:	3/21/2001
Examiner:	Ruth A. Davis
Art Unit:	1651
Confirmation Number:	1783

TRANSMITTAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following:

[X] Supplemental Reply Brief (14 pages).

[X] The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17 or §41.1 or 41.208, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions

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for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date 17 December 2007

By S. A. Bent

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Børge KRINGELUM, *et al.*

Title: **METHOD FOR SUPPLY OF STARTER CULTURES HAVING A CONSISTENT QUALITY**

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SUPPLEMENTAL REPLY BRIEF

Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Supplemental Reply Brief is in response to the Supplemental Examiner's Answer mailed October 25, 2007. Under the provisions of 37 CFR § 41.41, this Supplemental Reply Brief is timely filed within two months from the mailing date of the Supplemental Examiner's Answer.

Although no fee is believed to be associated with the present submission, Appellants hereby authorize the PTO to charge any deficiency and to credit any balance to deposit account 19-0741.

The Argument begins on page 4 of this document.

STATUS OF CLAIMS

Claims 1-31 are finally rejected and are the subject of this appeal. The pending claims are presented in Appendix A of this Brief.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection for review are as follows:

A. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski and Christensen.

B. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Christensen, and Czulak.

C. The rejection of claims 1-11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Christensen, and Lizak.

D. The rejection of claims 1-7, 11-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Vanderbergh, and Matsummiya.

E. The rejection of claims 1-7, 11, 17-22, 24-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Czulak, and Lizak.

F. The rejection of claims 1-7, 11, 17-27, and 29-31 under 35 U.S.C. § 103(a) over Sing in view of Kosikowski, Rimler, and Lizak.

ARGUMENT

I. Introduction

This supplemental reply brief comes to the Board in a convoluted way, as the following passages explain. Appellants maintain each argument of record in this appeal, even if it is not mentioned here.

Appellants' appeal brief, filed February 6, 2007, noted that they and the Examiner agree that the cited references as a whole fail to teach one element of the appealed claims, namely, *(b) ...providing a subset of starter cultures to a different...plant.* The effect on patentability of the missing element is the focus of disagreement. Claim 29 benefits from additional reasons of patentability that are not stated here but are elaborated elsewhere, for example, in Section VII A2 of the appeal brief.

Thus, Appellants have stated that the absence of element *(b)* from the prior art is fatal to the Examiner's position of unpatentability (Brief, p. 9 *ff*), because the presence of that element has a material impact on the claimed methodology. In particular, the declaration by Børge Kringelum attests that the claimed method, including element *(b)*, achieves results that are unexpected over conventional methodology, which lacks element *(b)*. According to the declaration, implementation of the claimed method has achieved an increase in product-approval rate of 5.25%. For a two-year production period, among Appellants' world-wide production factories, use of the claimed method yields a predicted total saving of US $1,500,000 annually (declaration, section 7), based on contemporaneous conversion rates.

The Examiner's Supplemental Answer addresses the declaration in a manner similar to that of record in the prosecution and urges **(A)** that the data presented in the declaration are not commensurate in scope with the claims; **(B)** that the standards used in the declaration are not equivalent, making the data unclear, and **(C)** that one of ordinary skill in the art would expect consistent quality. *See* Suppl. Answer, p. 4, 1st paragraph.

The present supplemental reply brief maintains each argument of record made in this appeal, even if it is not stated here, and primarily addresses points (A)-(C) made in the Supplemental Answer.

II. Response to the Supplemental Examiner's Answer

A. The appealed claims are commensurate in scope with the proffered declaration evidence

In her Supplemental Answer, the Examiner erroneously dismisses the proffered evidence of unexpected results on the grounds that they are "not commensurate in scope" with the appealed claims. Specifically, the Examiner asserts that she previously responded to the evidence in the declaration "in the Non-Final Office Action mailed on June 28, 2004, as well as the Final Office Action mailed on July 7, 2006" (Suppl. Answer, p. 4, ll. 1-3).

The final Office Action dated July 7, 2006, actually contains no commentary concerning the declaration, and the Examiner's Supplemental Answer reflects no substantive analysis on point. In the 2004 Office Action, the Examiner points out that ***one*** starter culture, R-603, experienced a higher approval rate with the conventional method than with the claimed methodology (p. 20, l. 19 through p. 21, l. 1).

In a response filed on April 17, 2006, Appellants submitted additional data to address the Examiner's concerns that R-603 has lower approval rate. *See* 2006 response, page 11, second paragraph *ff.* The table depicting the additional data is excerpted below from the 2006 response:

Data Collected Globally from 01 Oct 2001 to 01 March 2006

Bacterial culture	Produced per claimed invention	Discarded batches	Discarded (%)
FDVS R-603	223	3	1.3
FDVS R-604	629	6	1.0
PFD LA-1	230	1	0.4

In the declaration, relatively small numbers of batches, 7, 15, and 48 were tested for R-603, R-604, and LA-1 starter cultures, respectively. The additional data demonstrate that, when the number of batches for each culture was increased to 223, 629, or 230, only 1.3%, 1.0% or 0.4%

of the cultures was discarded, respectively. In other words, the approval rate for each of these cultures is 98.7%, 99% or 99.6%, which is significantly higher than the approval percentage for cultures generated by the conventional method, as shown in the declaration. Accordingly, the evidence on record amply supports the achievement of unexpected results with the claimed methodology.

Appellants submit, moreover, that the claimed invention is effective across a broad spectrum of cultures, a proposition that the result in question, involving a single species, do not contravene. Moreover, the declaration attests that the claimed method achieves 5.25% increase of the approval rate *in toto*. In other words, the claimed method is effective in increasing the approval rate of bacterial cultures overall, although it may not increase the approval rate for all species or for all species to the same extent.

Accordingly, there is no valid basis to Examiner's conclusion, drawn as it is to the alleged result with a single species. Even taken at face value, the Examiner's contention illuminates no scope-wise disjunction between the declaration evidence and the claimed invention. For this reason alone, her discounting of the declaration evidence constitutes reversible error.

B. <u>The results in the declaration are comparable</u>

The declaration states that "a number of 457 batches of commercial starter culture produced by the conventional method were compared with 115 batches produced by the method of the invention ***with regard to the percentage approved batches***" (section 6; emphasis added). Moreover, Table 1 compares the percentage of approved batches of the cultures produced by either method (columns 4 and 5, respectively).

One skilled in the art would have appreciated that statistical method allows one to compare the average of two observables, **A** and **B**, even if one measures observable **A** fewer times than observable **B**. Along these lines and by way of analogy, the Board is asked to take notice of the fact that in 2007 the average pendency of applications in GAU 1600 is 34.3 months while the average pendency of applications in GAU 2100 is 43.1 months. Even if the number of

applications differs in GAU 1600 and GAU 2100, it is not subject to a reasonable debate that the comparison of 34.3 months and 43.1 months should be clear. Yet, following the Examiner's reasoning, the comparison would be unclear and therefore ignored. The Board is asked to find (i) that the percentages of approved batches in the declaration are clear, capable of accurate and ready determination by resort to the raw data, and (ii) that the accuracy of these numbers cannot be reasonably questioned, because the declaration contrasts not the absolute number of the batches but rather the percentage of the approved batches, which is normalized.

C. The prior art does not teach that consistent quality can be achieved among different cultures

The Examiner's rational is that the results in the declaration are not unexpected because the prior art suggests consistent quality is achieved (Suppl. Answer, p. 4, ll. 5-7; and p. 6, ll. 4-8). First, if the results are "not unexpected," then why is the Examiner urging that the element absent from the references cited in the rejection is not material? Second, if the results are "not unexpected," then why is the Examiner urging that some members in the declaration have a higher rejection rate than others? Clearly, these positions are inconsistent.

In any case, the Examiner is not at the liberty to dismiss any unexpected results by simply not admitting to the significance of the results. To this end, the Examiner's position seems to be inconsistent. In the Supplemental Answer, the Examiner stated that "the data [do] not appear to evidence that a culture with consistently high quality is an unexpected result" (p. 4, ll. 6-7). In the 2004 Office Action, on the other hand, the Examiner acknowledges unexpected results for at least certain species, such as *B. bifidum* (p. 21, ll. 1-3).

The Examiner asserts that "the method obtained by the combination of cited references clearly identify and suggest to one in the art that a single starter culture can be used to inoculate multiple growth media. Thus, one in the art would expect a consistent quality between the various media that are inoculated by the starter culture." By this statement, the Examiner is heard to say that the skilled artisan would have expected a consistency of quality to arise when multiple cultures are obtained from the same starter, in accordance with the claimed invention.

Appellants submit that the Examiner's assertion in this regard is technically flawed and unsupported on the record. As one skilled in the art would have understood, the quality of each culture depends on many determinants besides the starter culture. For instance, the quality of each growth medium and manual manipulation of each culture may individually affect the quality of the particular culture. Therefore, the person of ordinary skill would have had no reason to expect consistent quality among different simply by virtue of a common starter culture.

Moreover, the unexpected results (a) are presented by parallel data obtained via conventional methodology versus the claimed method, (b) are supported by 5.25% increase of the approval rate and an annual saving of $1.5M, as noted above, and (c) are attested to by an expert in the field. Without any evidence of record to the contrary, it is improper to discount the unexpected results, therefore.

CONCLUSION

For above-discussed reasons and those presented in their main brief and reply brief, Appellants submit that the appealed rejections should be reversed in whole and that the pending claims should be sent to issue. Accordingly, they renew their request that the Board reverse the rejection.

Respectfully submitted,

Date 17 December 2007 By S. A. Bent

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APPENDIX A. CLAIMS INVOLVED IN APPEAL

1. A method of supplying starter cultures of consistent quality at different propagation factories or plants, comprising the steps of (i) providing inoculum material comprising starter culture organism cells, (ii) allowing the starter culture cells to propagate for a period of time sufficient to produce a desired amount of said starter culture organism cells, and (iii) harvesting the propagated cells to obtain a starter culture,

wherein step (i) comprises:

(a) concentrating said inoculum material of step (i) to obtain a concentrated stock inoculum material;

(b) dividing said concentrated stock inoculum material into subsets thereof and providing a subset to a different propagation factory or plant, each of said subsets having a quality sufficient to inoculate a cultivation medium at different propagation factories or plants, and

(c) inoculating said cultivation medium at the different propagation factory or plant with the subset of the stock inoculum material by direct, one step inoculation to produce said starter culture,

wherein said stock inoculum material is subjected to a quality test before use and is stored for at least 24 hours prior to said inoculating of the cultivation medium,

such that, when steps (ii) through (iii) are repeated with another subset of the stock inoculum material at a different propagation factory or plant, the supply of starter cultures has a consistent quality.

2. A method according to claim 1, wherein the inoculum material provided in step (i) is in quantities sufficient to inoculate at least 50,000 litres of cultivation medium.

3. A method according to claim 1, wherein the concentrated stock inoculum material provided in step (a) contains at least 10^8 CFU per g.

4. A method according to claim 1, wherein the subset of the stock inoculum material in step (c) is directly inoculated in the cultivation medium at a rate of maximum 0.1%.

5. A method according to claim 1, wherein the amount of the subset of the stock inoculum material for direct inoculation of the cultivation medium in step (c) provides a ratio of the CFU per g of cultivation medium, immediately after inoculation, relative to the CFU per g of the subset of the stock inoculum material being inoculated, said ratio being in the range from 1:100 to 1:100,000.

6. A method according to claim 1, wherein the cultivation medium immediately after the inoculation in step (c) contains a number of CFU per g of cultivation medium which is at least 10^5.

7. A method according to claim 1, wherein the cultivation medium in step (ii) comprises any conventional medium used for propagation of microbial cells.

8. A method according to claim 1, wherein the inoculum material and/or the subset of the stock inoculum material is in a state selected from the group consisting of a liquid, frozen and dried state.

9. A method according to claim 8, wherein the frozen subset of the stock inoculum material is thawed before direct inoculation of the cultivation medium in step (c).

10. A method according to claim 8, wherein the subset of the stock inoculum material is combined with an aqueous medium to obtain a suspension of the cells before direct inoculation of the cultivation medium in step (c).

11. A method according to claim 1, wherein the direct inoculation of the cultivation medium in step (c) is provided under aseptical conditions or under substantially aseptical conditions.

12. A method according to claim 1, wherein the stock inoculum material is supplied in sealed enclosures.

13. A method according to claim 12, wherein the sealed enclosures are made of a flexible material selected from the group consisting of a polyolefin, a substituted olefin, a copolymer of ethylene, a polypropylene, a polyethylene, a polyester, a polycarbonate, a polyamide, an acrylonitrile and a cellulose derivative.

14. A method according to claim 12, wherein the sealed enclosed are made of a flexible material comprising a metal foil.

15. A method according to claim 12, wherein the sealed enclosures have a cubic content of at least 0.01 litre.

16. A method according to claim 12, wherein the sealed enclosures are supplied with outlet means for connection of the enclosure to a container comprising the cultivation medium, said outlet means permitting the concentrate of cells to be introduced substantially aseptically into the container to inoculate the cultivation medium with said concentrate of cells.

17. A method according to claim 1, wherein the starter culture organism in step (i) originates from a species selected from the group consisting of a lactic acid bacterial species, a *Bifidobacterium* species, a *Propionibacterium* species, a *Staphylococcus* species, a *Micrococcus* species, a *Bacillus*, species, an *Actinomycetes* species, a *Corynebacterium* species, a *Brevibacterium* species, a *Pediococcus* species, a *Pseudomonas* species, a *Sphingomonas* species, a *Mycobacterium* species, a *Rhodococcus* species, an *Enterobacteriaceae* species, a fungal species and a yeast species.

18. A method according to claim 17, wherein the lactic acid bacterial species is selected from the group consisting of *Lactococcus* spp., *Lactobacillus* spp., *Leuconostoc* spp., *Pediococcus* spp., *Oenococcus* spp. and *Streptococcus* spp.

19. A method according to claim 1, wherein the inoculum material in step (i) comprises at least two starter culture strains.

20. A method according to claim 1, wherein the starter culture is a starter culture used in the food industry, feed industry or pharmaceutical industry.

21. A method according to claim 1, wherein the starter culture is used for inoculation of milk which is further processed to obtain a dairy product, which is selected from the group consisting of cheese, yogurt, butter, inoculated sweet milk and a liquid fermented milk product.

22. A method according to claim 1, wherein the cells being propagated in the cultivation medium express a desired gene product or produce a desired product.

23. A method according to claim 22, wherein the desired gene product is selected from the group consisting of enzymes, pharmaceutically active substances, polysaccharides and amino acids.

24. A method according to claim 22, wherein the desired product is selected from the group consisting of pigments, flavouring compounds, emulsifiers, vitamins, growth-stimulating compounds, food additives and feed additives.

25. A method according to claim 7, wherein the medium comprises one or more single milk components.

26. The method of claim 25, wherein one or more single milk components include skimmed milk.

27. The method of claim 1, wherein steps (ii) through (iii) are repeated with another subset of the stock inoculum material and wherein the supply of starter cultures resulting from each inoculation has a consistent quality.

28. The method of claim 1, wherein step (b) comprises providing a plurality of said subsets to different propagation factories or plants.

29. The method of claim 1, wherein the stock inoculum material or a subset thereof is subjected to a quality test selected from the group consisting of Test for contamination, Count of total viable cells, Determination of colony morphology, Determination of purity, Determination of metabolic activity, Phage test, API test, Resistance to bacteriophages, Determination of the content of *Listeria* species and salmonella species, DNA fingerprint, and Fermentation test.

30. The method of claim 1, wherein the stock inoculum material is stored for at least 48 hours prior to being added to the cultivation medium.

31. The method of claim 1, wherein the stock inoculum material or a subset thereof is transported or shipped to the different propagation factory or plant in a sealed enclosure.